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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
08 973,381	03 25 1998	NORMAND HEBERT	ISIS-2297	6836

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EXAMINER

MARSCHEL, ARDIN H

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 11 07 2002

*LD*

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**08 973,381**

Applicant(s)  
**Hebert**

Examiner  
**Ardin Marschel**

Art Unit  
**1631**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 a. In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. 35 U.S.C. § 133.
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704 b.

## Status

- 1) ☒ Responsive to communication(s) filed on Aug 20, 2002
- 2a) This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 31-56 is/are pending in the application.  
~~As of 08/20/02, claim(s) 1-30 have been canceled. (see withdrawal from prosecution)~~
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-56 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement

## Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are a) \_\_\_\_\_ accepted or b) \_\_\_\_\_ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) \_\_\_\_\_ approved b) \_\_\_\_\_ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some\* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |   |
|--|---|
| 1 <input checked="" type="checkbox"/> Notice of References Cited PTO-892 | 4 Interview Summary PTO-413 Paper No s          |
| 2 Notice of Draftsperson's Patent Drawing Review PTO-948                 | 5 Notice of Informal Patent Application PTO-152 |
| 3 Information Disclosure Statement s PTO-1449 Paper No s                 | 6 Other   |

Applicants' arguments, filed 8/20/02, have been considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Upon reconsideration, the following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

If applicant desires priority under 35 U.S.C. § 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. It is noted that this appears as the first sentence of the specification following the title. The status of non-provisional application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. \_\_\_\_\_" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application. Applicants' priority statement regarding parent applications seems to contain errors. It lacks a citation of the Patent No. 6,448,373 corresponding to Application Serial No. 08/179,970. It also seems to indicate that U.S. Patent No. 5,519,134 issued from Application Serial No. 08/179,970. PTO records indicate that this is not correct. Rather, U.S. Patent No. 5,519,134 seems to have issued from

Application Serial No. 08/180,134. Correction is required.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Only oligomeric compounds and combinatorial libraries are cited in the present title whereas the claims also include methods of preparation.

This application does not contain an Abstract of the Disclosure as required by 37 C.F.R. § 1.72(b). An Abstract on a separate sheet is required.

Claims 39-44 and 51-56 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 51, line 1, directs the method to preparing a library which is reasonably interpreted as being a plurality of entities therein. The remainder of claim 51, after the word "comprising" in line 1 cites a series of steps which seems to be directed to the preparation of a oligomeric compounds of aminodiol subunits which are cleaved from the support in the last step therein. Confusingly there are no limitations in claim 51 which are directed to what is normally thought of as a library preparation wherein the plurality of entities or polymers therein at least include different polymers rather than all of the polymers being the same. The performance of the actual preparatory steps of

claim 51 lacks any synthesis of different polymers. That is, the usage of a solid support upon which the preparation/synthesis of a single type of polymer of aminodiol subunits followed by cleavage is a reasonable interpretation of said preparatory steps. Thus, what is normally a library which is a mixture or plurality of different polymers is not required in the preparatory steps of claim 51. A pure single polymer preparation is what seems to be described in the actual preparatory steps of claim 51. Thus, the metes and bounds of claim 51 are different if controlled by the preamble versus the actual preparatory steps in the claim. Which part of claim 51 controls the metes and bounds of the claimed method? Clarification via clearer claim wording is requested. Claims 52-56 are included in this rejection because none of them require at least a different polymer or library preparatory step either. Additionally, the library claims 39-44 are rejected also as being unclear for the same issue that there are no claim limitations therein that require the claimed library to contain at least some different polymers.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*,

29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and  $\dot{}$  may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 31-44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,184,389. Although the conflicting claims are not identical, they are not patentably distinct from each other because the oligomeric compounds as claimed in said Patent are oligomers of species of the types of compound species in the instant claims designated as I or II with specific selections of -T-L, X, linking groups, and R groups. For example, in the instant claims, the choice of T being alkenyl of various lengths,  $R_{10}$  as =O, and L as thiol gives the various thienyl type of -T-L combinations of the claims of the Patent. The libraries thereof in the respective claim sets are contain these same compounds and are thus included in the respective claim sets.

Claims 45-56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,184,389 in view of either of Letsinger et al. (U.S. Patent No. 5,112,962) or

Smith et al. (U.S. Patent 5,015,733). The instant claims 45-56 are directed to the synthesis of oligomers of aminodiols having the structures cited in these claims including structure I or II as discussed in the above obviousness-type double patenting rejection. These type of oligomers are synthesized via monomer additions as described in Letsinger et al. or Smith et al. as normally carried out on a solid support with cleavage from said support at the end of the method. It is noted that such solid support synthesis with cleavage at the end of the completed oligomer is well known in oligomer synthesis, especially for oligomers made up of monomers as instantly claimed. The U.S. Patents of Letsinger et al. and Smith et al. are cited as supporting this well known oligomer synthesis technique on a solid support as well as cleavage of the final product from said support. Smith et al. summarizes and motivates such solid support synthetic methods in column 2, lines 19-47, and as depicted in Figure 3 in columns 3-4. Protecting groups as well as cleavage methods including base usage for said final cleavage is also motivated and summarized in column 5, line 67, through column 6, line 18. Similarly, Letsinger et al. depicts solid phase oligomer synthesis on the cover of the Patent and taken as a whole summarizes various labile anchors to improve the desired solid support cleavage reaction thus further motivating this practice.

Claims 31-56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-47 and 50-54 of U.S. Patent No. 6,448,373. Although the conflicting claims are not identical, they are not patentably distinct from each other because the oligomeric compounds, or processes for their preparation, as claimed in said Patent are oligomers of species of the types of compound species in the instant claims designated as I or II with specific selections of -T-L, X, linking groups, and R groups. The instant claims that are directed to library practice are included in this rejection because, as noted in the above rejection under 35 U.S.C. § 112, second paragraph, the instant library claims, including preparatory claims, confusingly seem to be interpretable as including pure polymer compositions and their preparation.

Alternatively, claims 31-56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-47 of U.S. Patent No. 6,448,373 in view of either of Letsinger et al. (U.S. Patent No. 5,112,962) or Smith et al. (U.S. Patent 5,015,733). The instant synthesis claims are directed to the synthesis of oligomers of aminodiols having the structures cited in these claims including structure I or II as discussed in the above obviousness-type double patenting rejection. These type of oligomers are



synthesized via monomer additions as described in Letsinger et al. or Smith et al. as normally carried out on a solid support with cleavage from said support at the end of the method. It is noted that such solid support synthesis with cleavage at the end of the completed oligomer is well known in oligomer synthesis, especially for oligomers made up of monomers as instantly claimed. The U.S. Patents of Letsinger et al. and Smith et al. are cited as supporting this well known oligomer synthesis technique on a solid support as well as cleavage of the final product from said support. Smith et al. summarizes and motivates such solid support synthetic methods in column 2, lines 19-47, and as depicted in Figure 3 in columns 3-4. Protecting groups as well as cleavage methods including base usage for said final cleavage is also motivated and summarized in column 5, line 67, through column 6, line 18. Similarly, Letsinger et al. depicts solid phase oligomer synthesis on the cover of the Patent and taken as a whole summarizes various labile anchors to improve the desired solid support cleavage reaction thus further motivating this practice. The instant claims that are directed to library practice are included in this rejection because, as noted in the above rejection under 35 U.S.C. § 112, second paragraph, the instant library claims, including preparatory claims, confusingly seem to be interpretable as including pure polymer compositions and their preparation.

Claims 31-44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 5,886,177. Although the conflicting claims are not identical, they are not patentably distinct from each other because the oligomeric compounds as claimed in said Patent are oligomers of species of the types of compound species in the instant claims designated as I with specific selections of -T-L, X, linking groups, and R groups. The instant claims that are directed to library practice are included in this rejection because, as noted in the above rejection under 35 U.S.C. § 112, second paragraph, the instant library claims, including preparatory claims, confusingly seem to be interpretable as including pure polymer compositions and their preparation.

Claims 45-56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 5,886,177 in view of either of Letsinger et al. (U.S. Patent No. 5,112,962) or Smith et al. (U.S. Patent 5,015,733). The instant claims 45-50 are directed to the synthesis of oligomers of aminodiols having the structures cited in these claims including structure I as discussed in the above obviousness-type double patenting rejection. These type of oligomers are synthesized via monomer additions as described in Letsinger et al. or Smith et al. as

normally carried out on a solid support with cleavage from said support at the end of the method. It is noted that such solid support synthesis with cleavage at the end of the completed oligomer is well known in oligomer synthesis, especially for oligomers made up of monomers as instantly claimed. The U.S. Patents of Letsinger et al. and Smith et al. are cited as supporting this well known oligomer synthesis technique on a solid support as well as cleavage of the final product from said support. Smith et al. summarizes and motivates such solid support synthetic methods in column 2, lines 19-47, and as depicted in Figure 3 in columns 3-4. Protecting groups as well as cleavage methods including base usage for said final cleavage is also motivated and summarized in column 5, line 67, through column 6, line 18. Similarly, Letsinger et al. depicts solid phase oligomer synthesis on the cover of the Patent and taken as a whole summarizes various labile anchors to improve the desired solid support cleavage reaction thus further motivating this practice. The instant claims that are directed to library practice are included in this rejection because, as noted in the above rejection under 35 U.S.C. § 112, second paragraph, the instant library claims, including preparatory claims, confusingly seem to be interpretable as including pure polymer compositions and their preparation.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31-38 and 45-56 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hebert (P/N 6,448,373), taken alone, or alternatively, taken in view of either of Smith et al. (P/N 5,015,733) or Letsinger et al. (P/N 5,112,962).

This rejection is based on the different inventorship for Hebert (P/N 6,448,373) versus the instant application and applied for the same subject matter reasons as set forth above in the obviousness-type double patenting rejections.

Applicant has provided evidence in this file showing that the invention was owned by, or subject to an obligation of assignment to, the same entity as the Hebert (P/N 6,448,373) reference at the time this invention was made. Accordingly, the Hebert (P/N 6,448,373) reference is disqualified as prior art through 35 U.S.C. § 102(f) or (g) in any rejection under 35 U.S.C. § 103(a) in this application. However, this reference additionally qualifies as prior art under section (e) of 35

U.S.C. § 102 and accordingly is not disqualified as prior art under 35 U.S.C. § 103(a).

Applicant may overcome the reference either by a showing under 37 CFR 1.132 that the invention disclosed therein was derived from the invention of this application, and is therefore, not the invention "by another", or by antedating the reference under 37 CFR 1.131.

The disclosure is objected to because of the following informalities:

In the specification on page 114, line 20, the word "diveritized" appears to be misspelled.

Appropriate correction is required.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina

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Plunkett, whose telephone number is (703)305-3524 or to the  
Technical Center receptionist whose telephone number is (703)  
308-0196.

November 6, 2002

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